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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,441	02/22/2005	Rebecca H. Li	08702.0110-00000	3832
22852	7590	10/01/2007		
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			EXAMINER HA, JULIE	
			ART UNIT 1654	PAPER NUMBER
			MAIL DATE 10/01/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/525,441

Applicant(s)

LI ET AL.

Examiner

Julie Ha

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 72-120 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 72-120 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 72-118, drawn to a composition for injectable delivery of osteogenic proteins comprising an osteogenic protein and a hyaluronic acid ester and the composition is in the form of a cylindrical rod.

Group 2, claim(s) 119, drawn to a method of making a composition.

Group 3, claim(s) 120, drawn to a method of treating a mammal having a bone defect comprising administering to the site of bone defect an effective amount of composition.

2. The inventions listed as Groups 1 to 3 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical feature is a composition for injectable delivery of osteogenic proteins comprising an osteogenic protein and a hyaluronic acid ester, wherein the composition is in the form of a cylindrical rod suitable for injecting or implanting in solid state into a body. Kim et al (US Patent # 7189392) teaches an injectable formulation for delivery of osteogenic protein. The compositions comprise an injectable formulation of hyaluronic acid esters and osteogenic protein and further provides processes for preparing injectable gel or paste formulations by transforming various non-woven pads and sponges of HA (see column 2, lines 40-46). Since the injectable composition is in gel or paste formulation and would be injected in a syringe-like apparatus, the composition is in cylindrical rod shape. Therefore, unity is broken.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

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The species are as follows:

Different bone morphogenic protein: BMP-2, BMP-4, BMP-5, BMP-6, BMP-7, BMP-10, BMP-12, BMP-13 or MP52,

Different excipient: pharmaceutically acceptable salts, polysaccharides, peptides, proteins, amino acids, synthetic polymers, natural polymers, or surfactants,

Resorption inhibitor: such as bisphosphonate,

Different bisphosphonate: alendronate, cimadronate, clodronate, EB-1053, etidronates, ibandronate, neridronate, opadronate, pamidronate, risedronate, tiludronate, YH 529, zolendronate, or pharmaceutically acceptable salts, esters, acids, or mixtures thereof,

Different % hyaluronic acid ester: 100%, 50%, 60%, 65%, 75%, 80%,

Different hyaluronic acid: such as Hyaff11p65, partially soluble particles, films, fibers, non-woven pads, or sponges

Different solvent: water, organic solvent or aqueous buffer.

4. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

5. If Group I is elected, the Applicant is required to elect a single disclosed species of bone morphogenic protein (BMP) and the hyaluronic acid and % of hyaluronic acid in the composition; if BMP composition further comprises an excipient, the Applicant is

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required to elect a single disclosed species of excipient; if BMP composition further comprises a bone resorption inhibitor, the Applicant is required to elect a single disclosed species of bone resorption inhibitor. For example, Applicant elects BMP-14, hyaluronic acid Hyaff11p65 in 50% and excipient is surfactant (cationic). Please note, if an election of a BMP and a hyaluronic acid is only elected, then a composition only comprising BMP and hyaluronic acid will only be examined. The other composition comprising other components, such as excipient or bone resorption inhibitor will not be examined and withdrawn from examination. If Group II is elected, the Applicant is required to elect a single disclosed species of BMP and hyaluronic acid for examination purposes. If Group III is elected, the Applicant is required to elect a single disclosed species of injectable composition, i.e., elect what is comprised in the injectable composition such as in Group I.

6. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

7. The claims are deemed to correspond to the species listed above in the following manner:

Claims 74, 80, 83, 84, 85, 100, 103, 104, 105 and 107.

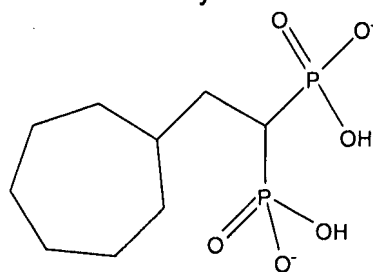
The following claim(s) are generic: claims 72-73, 81-82, 92, 99, 101-102, 106 and 119-120.

8. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or

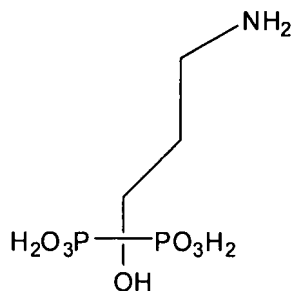
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corresponding special technical features for the following reasons: Different BMPs are patentably independent and distinct because each play a different function and are found in different chromosomes. For example, BMP-2 acts as a disulfide-linked homodimer and induces bone and cartilage formation, and is a candidate as a retinoid mediator. BMP-7 plays a key role in osteoblast differentiation, and plays a key role in renal development and repair. Further, search for one would not necessarily lead to the other. Different excipients are patentably independent and distinct because of their distinct structures. For example, polysaccharides are made up of sugar molecules while peptides, proteins and amino acids are made up of amino acids and forms peptide bonds. Further, search for one would not necessarily lead to the other. Different bisphosphonate are patentably independent and distinct because they all have different

structures. For example, cimadronate has the structure



while



alendronate has the structure . Further, search for one would not necessarily lead to the other. Different hyaluronic acids have different structural composition. For example, hyaluronic acid (HA) can be in a powder form, while other HA can be in non-woven fibers, pads, sponges etc. Sponges and pads are different composition from each other and powders are distinct from fibers, pads and sponges. Different solvents are patentably independent and distinct because of the solvent have different chemical formula and have different chemical properties. For example, water and ethanol have different freezing points and different chemical formula ( $\text{H}_2\text{O}$  vs.  $\text{CH}_3\text{-CH}_2\text{-OH}$ ). Further, search for one would not necessarily lead to the other.

9. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

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10. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

11. Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Conclusion***

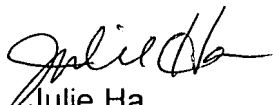
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie Ha whose telephone number is 571-272-5982.

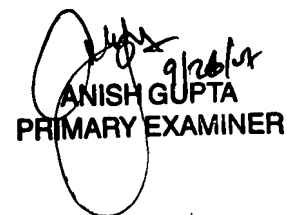
The examiner can normally be reached on Mon-Fri, 8:00 am to 4:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Julie Ha  
Patent Examiner  
AU 1654

  
ANISH GUPTA  
PRIMARY EXAMINER